12 HOUR ALLERGY D- cetirizine hcl, pseudoephedrine hcl tablet, extended release Meijer Distribution Inc

Meijer Distribution, Inc. 12 Hour Allergy-D Drug Facts

Active ingredient (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 120 mg

Purpose

Antihistamine

Nasal Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- · heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- do not use more than directed
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

do not break or chew tablet; swallow tablet whole

adults and children 12 years and over take 1 tablet every 12 hours; do not take more than 2 tablets in 24		
	hours.	
adults 65 years and over	ask a doctor	
children under 12 years of age	ask a doctor	
consumers with liver or kidney	ask a doctor	
disease		

Other information

• store between 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, yellow iron oxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Zyrtec-D® active ingredients

ALLERGY & CONGESTION

12 Hour Allergy-D

Cetirizine Hydrochloride and Pseudoephedrine Hyrdochloride

Extended Release Tablets 5 mg/120 mg

antihistamine/nasal decongestant

Indoor & Outdoor Allergies

12 Hour Relief of:

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat or Nose

Sinus Pressure

Nasal Congestion

Actual Size

Original Prescription Strength



■ temporarily restores freer breathing through

■ temporarily relieves sinus congestion and pressure ■ Legnces awelling of nasal passages ■ itching of the nose or throat ■ nasal congestion

fever or other upper respiratory allergies:

■ runny nose ■ sneezing ■ itchy,

itchying of the pose of the special itchy. ■ ітсһу, watery eyes

Drug Facts (continued)

■ temporarily relieves these symptoms due to hay

Cethrine HCl 5 mg.......Nasal Decongestant
Pseudoephedrine HCl 120 mg.....Nasal Decongestant enimstainitnA... Cetirizine HCI 5 mg..

(in each extended release tablet) Purpose Active ingredients

Drug Facts

NDC 41250-299-62



Compare to Zyrtec-D®

active ingredients*

12HourAllergy-

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended Release Tablets 5 mg/120 mg antihistamine/nasal decongestant

Indoor & Outdoor Allergies

12 Hour Relief of:

Sneezing

Itchy, Watery Eyes

Runny Nose

 Itchy Throat or Nose Sinus Pressure
 Nasal Congestion

24 Extended Release Tablets

Actual Size



Original Prescription Strength

Drug Facts (continued)

Warnings

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Ask a doctor before use if you have

- heart disease thyroid disease diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland ■ liver or kidney disease. Your doctor should determine
- if you need a different dose.

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Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

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Stop use and ask a doctor if

■ an allergic reaction to this product occurs. Seek medical help right away.

Drug Facts (continued)

- you get nervous, dizzy, or sleepless
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- if breast-feeding: not recommended
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- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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adults 65 years and over	ask a doctor	
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Other information

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Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, yellow iron oxide



DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Made in India
DIST. BY MEIJER DISTRIBUTION, INC.
2929 WALKER AVE NW
GRAND RAPIDS, MI 49544
www.meijer.com



Drug Facts (continued)

(Questions or comments? 1-800-719-9260

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Zyrtec-D®.



12 HOUR ALLERGY D

cetirizine hcl, pseudoephedrine hcl tablet, extended release

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:41250-299

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE UNII: YO726 1ME24) PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII: 7CUC 9 DD19 F) PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE HYDRO CHLO RIDE 120 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
TALC (UNII: 7SEV7J4R1U)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		

Product Characteristics			
Color	WHITE (one side white one side light yellow)	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	5029;5;120
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-299-53	2 in 1 CARTON	05/14/2008	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41250-299-62	4 in 1 CARTON	05/14/2008	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077170	07/15/1988	

Labeler - Meijer Distribution Inc (006959555)

Revised: 12/2018 Meijer Distribution Inc